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PATENT

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Michael W. Johnson
Application No.:	09/880,615
Filed:	June 13, 2001
For:	Stent Drug Delivery System
Examiner:	Jermie E. Cozart
Group Art Unit:	3726

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P.O. Box 1450  
Alexandria, VA 22313-1450

Docket No.: S63.2-6531-US03

## FACSIMILE TRANSMITTAL LETTER

TO: Examiner Johnson  
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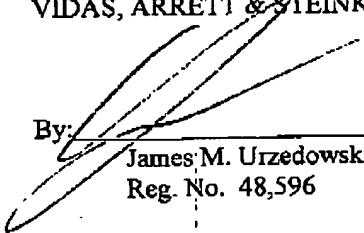
Following please find a 14 page Supplemental Brief on Appeal and 1 page Petition for an Extension of Time Under 37 CFR §1.136 in addition to this 1 page Facsimile Transmittal Letter.

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Respectfully Submitted,

VIDAS, ARRETT &amp; STEINKRAUS, P.A.

Date: October 24, 2005

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PATENT

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Docket No.: S63.2N-6531-US03

## SUPPLEMENTAL BRIEF ON APPEAL

This Supplemental Brief is in response to the Office Action dated June 24, 2005 in which prosecution was reopened. Reinstatement of the appeal is requested. The Examiner asserts that new grounds of rejection are set forth in reopening the prosecution. However, at the same time, the Examiner states that the previous arguments are unpersuasive. Further muddying the waters, the Examiner presents a "new" ground of rejection that is substantively identical to the previous grounds for rejection. The new ground again rejects claims 23-24, 26-30, 32-33, and 35-40 while using the same prior art references as before.

Applicant asserts that the reopening of prosecution is improper as the Examiner has not in fact provided new grounds of rejection. There is no new ground of rejection when the basic thrust of the rejection remains the same such that an appellant has been given a fair opportunity to react to the rejection. See *In re Kronig*, 539 F.2d 1300, 1302-03, 190 USPQ 425, 426-27 (CCPA 1976). The arguments used by the Examiner are substantively the same as those presented in the Office Action dated November 26, 2004. The Examiner basically provided those same arguments with the addition of language asserting the obviousness of some of the

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dependent claims. Furthermore, where the statutory basis for the rejection remains the same, and the evidence relied upon in support of the rejection remains the same, a change in the discussion of, or rationale in support of, the rejection does not necessarily constitute a new ground of rejection. *Id.* at 1303, 190 USPQ at 427. The “new” grounds for rejection provided by the Examiner have the same statutory basis of 103(a) obviousness and utilize in the first rejection the same evidence of Yan and Solovay and in the second rejection the evidence of Yan, Solovay, and Richter all of which were prior art references previously presented in the Office Action of November 26, 2004. For these reasons, Applicant believes that the reopening of prosecution for the stated reasons is improper and that the “new” arguments should not be considered.

Nevertheless, Applicant responds to these arguments below.

**(i) Real Party in Interest**

*(i) Real party in interest. A statement identifying by name the real party in interest.*

The application is assigned to Boston Scientific Scimed, Inc., (former name: Scimed Life Systems, Inc.), One SciMed Place, Maple Grove, MN 55311-1566, a Minnesota Corporation and a subsidiary of Boston Scientific Corporation, One Boston Scientific Place, Natick, Massachusetts, 01760-1537, a Delaware Corporation.

**(ii) Related Appeals and Interferences**

*(ii) Related appeals and interferences. A statement identifying by application, patent, appeal or interference number all other prior and pending appeals, interferences or judicial proceedings known to appellant, the appellant's legal representative, or assignee which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal. Copies of any decisions rendered by a court or the Board in any proceeding identified under this paragraph must be included in an appendix as required by paragraph (c)(1)(x) of this section.*

Applicant submitted an Appeal Brief that was filed on April 25, 2005 under the same application number as in this Supplemental Appeal Brief.

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**(iii) Status of claims**

*(iii) Status of claims. A statement of the status of all the claims in the proceeding (e.g., rejected, allowed or confirmed, withdrawn, objected to, canceled) and an identification of those claims that are being appealed.*

Claims 23-24, 26-33, and 35-41 are pending and have been rejected. Of these, claims 31 and 41 have been withdrawn. Claims 1-22, 25, and 34 have been canceled. No claims have been allowed or objected to. The claims that are being appealed are 23-24, 26-30, 32-33, and 35-40.

**(iv) Status of amendments**

*(iv) Status of amendments. A statement of the status of any amendment filed subsequent to final rejection.*

No amendment was filed subsequent to the final rejection November 26, 2004.

**(v) Summary of claimed subject matter**

*(v) Summary of claimed subject matter. A concise explanation of the subject matter defined in each of the independent claims involved in the appeal, which shall refer to the specification by page and line number, and to the drawing, if any, by reference characters. For each independent claim involved in the appeal and for each dependent claim argued separately under the provisions of paragraph (c)(1)(vii) of this section, every means plus function and step plus function as permitted by 35 U.S.C. 112, sixth paragraph, must be identified and the structure, material, or acts described in the specification as corresponding to each claimed function must be set forth with reference to the specification by page and line number, and to the drawing, if any, by reference characters.*

Claims 23-24 and 26-30 pertain to a method for manufacturing a stent from a tube. The required references to the specification and drawings are provided in brackets in the claim summaries below.

The invention, as recited in claims 23-24 and 26-30 provides a novel method by which a stent having at least two different longitudinally spaced regions of different predetermined porosity is manufactured.

According to independent claim 23, a tube is provided [p. 4, ln. 22; p. 8, ln. 26; p. 9, ln. 2].

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The tube has at least two different longitudinally spaced regions of different predetermined porosities [p. 7, ln. 10-16; p. 8, ln. 5-6; p. 9, ln. 7-9; Fig. 5]. Fig. 5 illustrates these regions in a stent that has been cut from such a tube.

Each region has substantially the same porosity about its circumference [p. 6, ln. 15-19, Fig. 5]. The longitudinally spaced regions are again illustrated in the stent of Fig. 5 and are shown to have substantially the same porosity about a given circumference.

A stent is *then* cut from the tube [p. 5, ln. 4-5; p. 8, ln. 14].

According to independent claim 32, a tube is provided [p. 4, ln. 22; p. 8, ln. 26; p. 9, ln. 2]. The tube has at least two different longitudinally spaced regions of different predetermined porosities [p. 7, ln. 10-16; p. 8, ln. 5-6; p. 9, ln. 7-9; Fig. 5]. A plurality of openings are cut in the tube to form a stent [p. 5, ln. 4-5; p. 8, ln. 14; Fig. 5]. The stent has multiple serpentine bands such that a first band has a different porosity than a second band [p. 6, ln. 19-20; Fig. 5].

**(vi) Additional Grounds of Rejection to be Reviewed on Appeal**

*(vi) Grounds of rejection to be reviewed on appeal. A concise statement of each ground of rejection presented for review.*

Review on appeal is requested of the Examiner's contention that claims 23, 26, 29, and 30 are obvious from Yan (U.S. 5,843,172) in view of Solovay (U.S. 5,769,884).

Review on appeal is also requested of the Examiner's contention that claims 24, 33, 38, and 40 are obvious from Yan and Solovay and further in view of Richter (5,807, 404).

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**(vii) Argument**

*(vii) Argument. The contentions of appellant with respect to each ground of rejection presented for review in paragraph (c)(1)(vi) of this section, and the basis therefor, with citations of the statutes, regulations, authorities, and parts of the record relied on. Any arguments or authorities not included in the brief or a reply brief filed pursuant to §41.41 will be refused consideration by the Board, unless good cause is shown. Each ground of rejection must be treated under a separate heading. For each ground of rejection applying to two or more claims, the claims may be argued separately or as a group. When multiple claims subject to the same ground of rejection are argued as a group by appellant, the Board may select a single claim from the group of claims that are argued together to decide the appeal with respect to the group of claims as to the ground of rejection on the basis of the selected claim alone. Notwithstanding any other provision of this paragraph, the failure of appellant to separately argue claims which appellant has grouped together shall constitute a waiver of any argument that the Board must consider the patentability of any grouped claim separately. Any claim argued separately should be placed under a subheading identifying the claim by number. Claims argued as a group should be placed under a subheading identifying the claims by number. A statement which merely points out what a claim recites will not be considered an argument for separate patentability of the claim.*

- 1. The Examiner further erred in rejecting Claims 23, 26-30, 32, 35-37, and 39 as obvious over Yan (U.S. 5,843,172) in view of Solovay (U.S. 5,769,884).**

Claims 23, 26-30, 32, 35-37, and 39 have been rejected under 35 USC 103(a) over Yan (U.S. 5,843,172) in view of Solovay (U.S. 5,769,884). The rejection must be reversed.

The Examiner has not made the requisite showing to support an obviousness rejection. Claims 23, 26-30, 32, 35-37, and 39 require the step of "providing a tube [...] having at least two different longitudinally spaced regions of different predetermined porosities".

In regard to claim 23 and those claims dependent thereof, the Examiner has repeatedly asserted throughout the prosecution of this application that Yan discloses providing a tube having at least two different longitudinally spaced regions of different predetermined physical characteristics (specifically, different predetermined porosities). Likewise, regarding claim 32 and those claims dependent thereof, the Examiner has repeatedly asserted throughout the prosecution of this application that Yan discloses providing a tube having at least two different longitudinally spaced regions of different predetermined porosities.

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In multiple responses to both these assertions, Applicant has pointed out that this is not consistent with column 4 lines 58-64 of Yan which teaches uniform porosity and the undesirability of areas of different porosity. As the explicit language of the Yan reference teaches the undesirability of areas of different porosity, it does not make sense that Yan would teach longitudinally spaced regions of different predetermined physical porosities. In fact, Yan teaches away from such a teaching; one would never predetermine to produce the very thing that is undesirable (i.e. non-uniform porosity).

As such, the obviousness rejection cannot be maintained. The combination of Yan and Solovay is impermissible for lack of motivation as one of the references (Yan) teaches away from the very combination proposed by the Examiner. For at least this reason, Applicant respectfully requests that the obviousness rejection be withdrawn.

**2. The Examiner further erred in rejecting Claims 24, 33, 38, and 40.**

Claims 24, 33, 38, and 40 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Yan and Solovay and further in view of Richter (5,807, 404). The rejection must be reversed.

The Examiner has not made the requisite showing to support an obviousness rejection. Dependent claims 24, 33, 38, and 40 require the step of "providing a tube [...] having at least two different longitudinally spaced regions of different predetermined porosities" as recited in claims 23 and 32. Neither Yan nor Solovay teach or suggest this claim element. One cannot look to the teaching of Richter to provide this teaching. Motivation to make the combination is lacking in that Richter neither teaches nor suggests the desirability of providing a

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stent with different porosities. Additionally, motivation to make the combination is lacking in Solovay which discloses a stent covering for use on a stent without any suggestion of the porosity being within the stent itself. For at least these reasons, reversal of the rejection under 35 USC §103 is respectfully requested.

Furthermore, the combination of Yan, Solovay, and Richter does not teach or suggest providing a tube having at least two different longitudinally spaced regions of different predetermined porosities and subsequently cutting the tube into a stent. The stent cover of Solovay functions properly when placed about a stent and there is no disclosure that it possesses the requisite stent quality of a structure capable of supporting a body lumen. Thus, any cutting performed on the tube in Solovay does not form a stent as claimed in claim 23 or claim 32; instead it forms a stent cover which is then placed about a stent. A skilled person in the art will not look to the stent cover art to find a method for manufacturing a stent having longitudinally spaced regions of different predetermined porosities.

To the extent that one of ordinary skill in the art were presented with the above-mentioned references, at most one would provide the stent of Richter with the cover of Solovay. This would not, however, render obvious the claimed method. Providing a stent cover of different porosities to an already cut stent is not the same as providing a tube of at least two different longitudinally spaced regions of different predetermined porosities and then cutting a stent from the tube. Nothing in any of the applied references suggest first providing the recited tube of different porosities and then cutting the stent from the tube.

Moreover, even if, for the sake of argument only, one were to take from Solovay a broad teaching that the stent itself may be provided with the different regions of different predetermined porosities, nevertheless, the proposed combination would not teach whether the



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different porosities should be provided prior to cutting the stent or after cutting the stent. To that end, we note that Solovay teaches laser drilling as one means of providing a stent cover with the desired porosity. Laser drilling prior to cutting the stent would likely result in an inefficient process as portions of the tube that will be discarded are drilled. Thus, in this case, one would not be led to provide a tube with the desired porosities and then cut a stent. Rather one would cut the stent first and then provide it with the different porosities, contrary to the recitations of the claim.

Furthermore, the Examiner often points to the stent produced rather than the method of producing the stent in trying to show obviousness. The first limitation of claims 23 and 32 requires providing a tube having at least two different longitudinally spaced regions of different predetermined porosities; the second limitation is *subsequently* cutting a plurality of openings in the tube to form a stent. The only openings cut in the stent covering of Solovay are the pores themselves. Thus, there is no subsequent cutting to form a stent and the limitation is not met.

In addition, if one were to take the stent cover of Solovay and then cuts it as one would in forming a stent, the very purpose of the Solovay stent cover would be destroyed; the stent cover would at best now sparsely and intermittently cover the stent and the struts of the stents and would likely interfere with stent expansion as the serpentine portions of the cut stent cover would become tangled with the serpentine bands of the stent.

Finally, the Examiner is using the impermissible benefit of hindsight when rejecting claims 23 and 32 for obviousness. The Examiner has not shown any teaching or motivation to combine the references. Motivation to make the combination is lacking in both Richter and Yan in that neither suggests the desirability of providing a stent with different

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porosities. Likewise, motivation to make the combination is lacking in Solovay which discloses a stent covering for use on a stent without any suggestion of the porosity being within the stent itself.

The Examiner has not identified a reasonable motivation to combine the Yan, Solovay, and Richter patents and has not shown how any combination of teachings in these documents could produce the invention of any of the claims, let alone claims 23, 24, 26-30, 32, 33, 35-40. For at least these reasons, reversal of the rejection under 35 USC §103 is respectfully requested.

### **3. Conclusion**

The Examiner has not shown motivation to combine the references and even when combined the teachings of these patents still fail to teach or suggest the method of any of the claims 23, 24, 26-30, 32, 33, and 35-40. Claims 23, 24, 26-30, 32, 33, and 35-40 therefore are not obvious from Yan in view of Solovay or from Yan in view of Solovay and Richter. The Board is respectfully requested to reverse the rejections with instruction to pass the application to issue.

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Respectfully submitted,

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**(viii) Claims Appendix**

*(viii) Claims appendix. An appendix containing a copy of the claims involved in the appeal.*

Claims 1-22. (Canceled)

Claim 23. (Previously presented) A method of manufacturing a stent comprising the steps of: providing a tube, the tube characterized by a longitudinal axis, having at least two different longitudinally spaced regions of different predetermined porosities and each region having substantially the same porosity about its circumference, and subsequently cutting a stent from the tube.

Claim 24. (Previously presented) The method of claim 23 wherein a first portion of the tube is made from a first metal and a second portion of the tube, axially spaced from the first portion of the tube is made from a second metal different from the first metal.

Claim 25. (Canceled)

Claim 26. (Previously presented) The method of claim 23 further comprising the step of disposing a treatment agent on the stent.

Claim 27. (Previously presented) The method of claim 23 wherein the stent includes a plurality of serpentine segments extending about the circumference of the stent.

Claim 28. (Previously presented) The method of claim 23 wherein the cutting step includes forming a plurality of serpentine segments which extend about the circumference of the stent.

Claim 29. (Previously presented) The method of claim 23 wherein the cutting step includes forming a plurality of openings which are elongate.

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Claim 30. (Previously presented) The method of claim 23 wherein the cutting step includes forming a plurality of openings whose widths exceed their lengths.

Claim 31. (Withdrawn) A stent formed in accordance with the method of claim 23.

Claim 32. (Previously presented) A method of manufacturing a stent comprising the steps of: providing a tube having at least two different longitudinally spaced regions of different predetermined porosities; and subsequently, cutting a plurality of openings in the tube to form a stent having multiple serpentine bands such that a first band has a different porosity than a second band.

Claim 33. (Previously presented) The method of claim 32 wherein a first portion of the tube is made from a first metal and a second portion of the tube, axially spaced from the first portion of the tube is made from a second metal different from the first metal.

Claim 34. (Canceled)

Claim 35. (Previously presented) The method of claim 32 further comprising the step of disposing a treatment agent on the stent.

Claim 36. (Previously presented) The method of claim 32 wherein at least some of the openings are bounded at a proximal end by a first serpentine segment and at a distal end by a second serpentine segment.

Claim 37. (Previously presented) The method of claim 36 wherein the openings which are bounded at a proximal end by a first serpentine segment and at a distal end by a second serpentine segment include a first side wall and a second side wall extending between and connecting the first and second serpentine segments.

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Claim 38. (Previously presented) The method of claim 37 wherein the first and second side walls are non-parallel to the longitudinal axis of the stent.

Claim 39. (Previously presented) The method of claim 32 wherein at least some of the openings are bounded at a proximal end by a first serpentine segment and at a distal end by a second serpentine segment, the first and second serpentine segments having different physical characteristics.

Claim 40. (Previously presented) The method of claim 32 wherein at least some of the openings are bounded at a proximal end by a first serpentine segment made of a first metal and at a distal end by a second serpentine segment made of a second metal different from the first metal.

Claim 41. (Withdrawn) A stent formed in accordance with the method of claim 32.

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(ix) *Evidence appendix.* An appendix containing copies of any evidence submitted pursuant to §§1.130, 1.131, or 1.132 of this title or of any other evidence entered by the examiner and relied upon by appellant in the appeal, along with a statement setting forth where in the record that evidence was entered in the record by the examiner. Reference to unentered evidence is not permitted in the brief. See §41.33 for treatment of evidence submitted after appeal. This appendix may also include copies of the evidence relied upon by the examiner as to grounds of rejection to be reviewed on appeal.

Not applicable

(x) *Related proceedings appendix.* An appendix containing copies of decisions rendered by a court or the Board in any proceeding identified pursuant to paragraph (c)(1)(ii) of this section.

Not applicable

(2) A brief shall not include any new or non-admitted amendment, or any new or non-admitted affidavit or other evidence. See §1.116 of this title for amendments, affidavits or other evidence filed after final action but before or on the same date of filing an appeal and §41.33 for amendments, affidavits or other evidence filed after the date of filing the appeal.

(d) If a brief is filed which does not comply with all the requirements of paragraph (c) of this section, appellant will be notified of the reasons for non-compliance and given a time period within which to file an amended brief. If appellant does not file an amended brief within the set time period, or files an amended brief which does not overcome all the reasons for non-compliance stated in the notification, the appeal will stand dismissed.

(e) The time periods set forth in this section are extendable under the provisions of §1.136 of this title for patent applications and §1.550(c) of this title for ex parte reexamination proceedings.